

**Australian Government** 

# **Department of Health**

# Therapeutic Goods Administration

**Public Summary** 

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

#### Products

## 1. MediHerb Livton Complex

Product Type	Single Medicine Product	Effective Date	5/03/2021	
Permitted Indications				
Antioxidant/Reduce free radicals formed in the body				
Helps reduce/decrease free radical damage to body cells				
Traditionally used in Western herbal medicine to helps maintain/support body's natural channels of elimination				
Traditionally used in Western herbal medicine to aids/assists natural body cleansing/detoxification processes				
Traditionally used in Western herbal medicine to maintain/support natural body cleansing/detoxification processes				
Traditionally used in Western herbal medicine to aids/assists natural cleansing/detoxification processes of the gastrointestinal system/gut				
Traditionally used in Western herbal medicine to maintain/support natural cleansing/detoxification processes of the gastrointestinal system/gut				
Traditionally used in Western herbal medicine to maintain/support natural liver cleansing/detoxification processes				
Traditionally used in Western herbal medicine to aids/assists excretion of metabolic waste products				
Traditionally used in Western herbal medicine to aids/assists body waste elimination				
Traditionally used in Western herbal medicine to maintain/support body waste elimination				
Traditionally used in Western herbal medicine to maintain/support general health and wellbeing				
Traditionally used in Western herbal medicine to maintain/support healthy digestive system function				
Traditionally used in Western herbal medicine to maintain/support digestive system health				
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia				
	Decrease/reduce/relieve flatulence/carminative Decrease/reduce/relieve abdominal feeling of fullness			
Linked indication - I	Decrease/reduce/relieve abdominal bloating/distention			
	Relieve digestive discomfort			
Traditionally used in Western herbal medicine to cholagogue/promote bile flow from gall bladder				
Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver				
Traditionally used in Western herbal medicine to liver tonic/Enhance liver health				
Traditionally used in Western herbal medicine to promote bile flow from liver/chloretic				
Traditionally used in Western herbal medicine to maintain/support bile production				
Traditionally used in Western herbal medicine to maintain/support healthy liver function				
Traditionally used in Western herbal medicine to maintain/support liver health				
Indication Requirements				

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Therapeutic Goods Administration

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to disease in any body organ.

Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

#### **Standard Indications**

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

# Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

If symptoms persist, seek the advice of a healthcare professional.

For practitioner dispensing only.

### Additional Product information

Pack Size/Poison information	
Pack Size	Poison Schedule
Components	
1 . Formulation 1	
Dosage Form Tablet, film coated	
Route of Administration Oral	
Visual Identification	
Active Ingredients	
Bupleurum falcatum root Extract liquid	600 microlitre
Equivalent: Bupleurum falcatum (Dry)	300 mg
Chionanthus virginica stem bark Extract liquid	320 microlitre
Equivalent: Chionanthus virginica (Dry)	160 mg
Cynara scolymus leaf Extract dry concentrate	200 mg
Equivalent: Cynara scolymus (Dry)	800 mg
Silybum marianum seed Extract dry concentrate standardised	114.29 mg
Equivalent: Silybum marianum (Dry)	8 g
Taraxacum officinale root Extract liquid	800 microlitre
Equivalent: Taraxacum officinale (Dry)	400 mg
Other Ingredients (Excipients)	
calcium hydrogen phosphate dihydrate	

colloidal anhydrous silica

croscarmellose sodium

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

sodium starch glycollate

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